



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0964]

Eduardo Navarro: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Eduardo Navarro from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Navarro was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Mr. Navarro was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of December 24, 2021 (30 days after receipt of the notice), Mr. Navarro had not responded. Mr. Navarro's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On August 11, 2021, Mr. Navarro was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Southern District of Florida, Miami Division, when the court accepted his plea of guilty and entered judgment against him for one count of Conspiracy to Defraud the United States in violation of 18 U.S.C. 371.

The factual basis for this conviction is as follows: As contained in the Information, entered into the docket on March 16, 2021, and the Factual Proffer in Support of his guilty plea, entered into the docket on June 8, 2021, both from his case, Mr. Navarro was an advanced Registered Nurse Practitioner employed as a sub-investigator at Tellus Clinical Research (Tellus) under the direction of a clinical investigator. Tellus was a medical clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. A drug manufacturer (Sponsor) initiated a clinical trial concerning a new investigational drug intended to treat patients suffering from irritable bowel syndrome (Study or IBS Trial). The Sponsor retained a Contract Research Organization (CRO) to manage various aspects of the IBS Trial. The CRO entered into a contract with Tellus and Martin Valdes, a medical doctor serving as a clinical investigator for clinical trials conducted at Tellus and as the clinical investigator for the IBS Trial. The study protocol for the IBS trial required subjects to make periodic scheduled visits to the clinical trial site for which they were paid \$100 per visit. During some of these visits, subjects were required

to provide blood samples for pharmacokinetic analysis, receive physical exams by clinical trial staff, and undergo electrocardiograms. Subjects were also required to use an “e-diary” system to report their daily experience with the Study drugs. They would do this by making daily phone calls to a number maintained by a third party and answering automated questions nonverbally by touch-tone buttons.

In his role as a sub-investigator, Mr. Navarro was responsible for conducting physical exams on subjects, reviewing lab work and electrocardiograms, and preparing case histories reflecting the participation of subjects in the Study. However, Mr. Navarro and his co-conspirators engaged in an effort to impair, impede, and obstruct FDA’s legitimate function of regulating clinical trials of drugs in order to obtain money. Mr. Navarro and his co-conspirators did this by fabricating medical records to portray persons as legitimate Study subjects when they were not. He and his co-conspirators falsified these records to make it appear that the Study subjects had consented to participating in the Study, satisfied the Study’s eligibility criteria, appeared for scheduled visits at the Study’s site, taken Study drugs as required, and received checks as payment for site visits, among other things. For example, Mr. Navarro represented that he had seen a purported Study subject and performed a physical examination of her when he knew she was not a Study subject and these representations were false. Mr. Navarro also knew that one or more of his co-conspirators placed telephone calls to the e-diary system for the purposes of reporting fabricated data on behalf of purportedly legitimate Study subjects.

As a result of this conviction, FDA sent Mr. Navarro by certified mail on November 8, 2021, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Navarro was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Mr. Navarro an opportunity to request a

hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Navarro received the proposal on November 24, 2021. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Navarro has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Navarro is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see section 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Navarro in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Navarro provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Navarro during his period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a “drug product” is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355,

360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Navarro for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2021-N-0964 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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